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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,920	07/24/2001	Cho-Chou Kuo	41548	2753

23373 7590 08/18/2003

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT	PAPER NUMBER
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1645

19

DATE MAILED: 08/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/910,920

Applicant(s)

KUO ET AL.

Examiner

Padmavathi v Baskar

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--Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 June 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☒ Applicant's reply has overcome the following rejection(s): see attached note.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached note.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: NONE.Claim(s) objected to: NONE.Claim(s) rejected: 1-4, 6, 8, 17 and 18.Claim(s) withdrawn from consideration: 9-16.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

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ADVISORY ACTION

1. Applicant's amendment filed on 6/5/03 is entered. Claim 1 has been amended. Claims 1-4, 6, 8 and 17-18 are pending.
2. In view of the executed Declaration (submitted under 37C.F.R 1.131), the rejection of claims 1- 4, 6, 8 and 17-18 under 35 U.S.C. 102 (a) as being anticipated by Lin et al 2001 is withdrawn.
3. In view of amendment to the claim 1, the rejection of claim 8 under 35 U.S.C. 112, second paragraph is withdrawn.
4. The rejection of claims 1 and 8 under 35 U.S.C. 102 (b) as being anticipated by Kuo et al 1996 is maintained as set forth in the previous office action (paper # 12).

Applicants' arguments filed on 6/5/03 have been fully considered but they are not deemed to be persuasive.

Applicant continues to argue that (1) there is no evidence that Hela cells pretreated with oligosaccharide interact with mannose-6-phosphate, (2) pretreated Hela cells with oligosaccharides is not a "molecule" as required by the claim and (3) claims do not recite composition that inhibits infectivity interacts with mannose-6-phosphate and therefore, the rejection is improper.

The claims are rejected because the claim requires a composition comprising Chlamydia inhibiting amount of a molecule (s) that interacts with mannose-6-phosphate and mannose -6-phosphate receptor and such composition was disclosed by Kuo et al i.e., a composition comprising a high mannose type oligosaccharide) associated with MOMP bind to mannose -6-phosphate receptor on the cells and thus this composition inhibited infectivity of Chlamydia in

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Hela cells (see Figures 2 and 3). Therefore, both molecules and composition are disclosed by the prior art and therefore, this rejection is maintained.

5. The rejection of claims 1-4, 6 and 8 under 35 U.S.C. 102 (b) as being anticipated by Ooij et al 1997 is maintained as set forth in the previous office action (paper # 12).

Applicants' arguments filed on 6/5/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that this rejection is made in hindsight because the specification and the discovery of applicant's invention teach that a molecule that reacts with mannose-6-phosphate can also inhibit infection.

It is the position of the Examiner that the claims are rejected based on the facts available in the state of the prior art and not based on applicant's disclosure as hindsight.

The state of the art (see Kuo et al 1996) indicates that an N-linked high mannose type oligosaccharide, expressed at the major outer membrane protein of Chlamydia mediates attachment and infectivity. Therefore, the rejection is maintained.

6. The rejection of claims 17-18 under 35 U.S.C. 102 (b) as being anticipated by Ooij et al 1997 is maintained as set forth in the previous office action (paper # 12).

The claims are drawn to a composition comprising Chlamydia inhibiting amount of a molecule that interacts with insulin-like- growth-factor-2 (IGF-2) in a pharmaceutical composition, said molecule an antibody. Ooij et al. (Infect. Immun. 1997 Vol. 65(2) pp. 758-766) disclose a composition comprising monoclonal antibody to mannose-6-phosphate receptor (see page 759, left column, second paragraph) in a pharmaceutical composition i.e., PBS (see page 759, left column last three lines of last paragraph). This antibody binds to infected C.trachomatis cells that contain mannose-6-phosphate receptors. It is known that IGF-2 binds to mannose-6-phosphate receptor (IGF-2/Man6-p receptor, see Specification pages 4-5). Therefore, antibodies to mannose-6-phosphate receptor would interact with IGF-2. Hence, antibodies to mannose-6-phosphate receptor read on the claimed Chlamydia infection-inhibiting amount of molecules. Since the Office does not have the facilities for examining and comparing applicants' product with the product of the prior art, the burden is on applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald et al.*, 205 USPQ 594.

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Applicants' arguments filed on 6/5/03 have been fully considered but they are not deemed to be persuasive.

Applicant continues to argue about the term "molecule" and states that this rejection is incorrect because a " molecule " as recited in the claims does not include a composition comprising cells and the examiner misinterpreted the term "molecule".

It is the position of the examiner that the specification, pages 5, lines 7-10 states that

" The molecules used to intervene in the binding of Chlamydia to the host cell can be of any origin, natural or synthetic, so long as the molecule engages the receptor and ultimately preventing attachment of Chlamydia to the cell surface". Therefore, the examiner correctly used the cited antibodies to mannose-6-phosphate receptor as they interact with receptor and inhibit the Chlamydia binding to the cell surface and thereby inhibiting the infection. Since IGF-2 binds to mannose-6-phosphate receptor, the antibodies that bind to mannose-6-phosphate receptor bind to IGF-2.

7. The rejection of claims 17-18 under 35 U.S.C. 102 (b) as being anticipated by Peterson et al 1998 (Infect. Immun. Vol. 66(8) pp3848-3855) is maintained as set forth in the previous office action (paper # 12).

The claims are drawn to a composition comprising Chlamydia inhibiting amount of a molecule that interacts with insulin-like- growth-factor-2 (IGF-2) in a pharmaceutical composition, said molecule an antibody.

Peterson et al (Infect. Immun. 1998) disclose a composition comprising a monoclonal antibody Mab CP-33. This antibody neutralized the infectivity of Chlamydia pneumoniae (see abstract and figure 4). Therefore, the disclosed antibody meets the limitation "a composition comprising Chlamydia inhibiting amount of a molecule". Pharmaceutical carrier or diluent read on medium or water or PBS (see page 3849 right column, under in vitro neutralization assay). Mab CP-33 specifically inhibits Chlamydia (see discussion, page 3852, right column, second paragraph, Table 1 and 2) and neutralizes the infection. Therefore, it is inherent that this antibody interacts with insulin-like- growth-factor-2 because the antibody interacts with mannose 6-phosphate and thereby interacting with IGF-2. These antibodies inhibited the infection compared to normal controls (see Table 1 and 2) in Hep-2 or Hela cells that contain mannose-6-phosphate receptor. It is known that IGF-2 binds to mannose-6-phosphate receptor (IGF-

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2/Man6-p receptor, see Specification pages 4-5). The prior art anticipated the claimed invention.

Applicants' arguments filed on 6/5/03 have been fully considered but they are not deemed to be persuasive.

Applicant states that antibodies to CP33 could not possibly bind to insulin-like- growth-factor-2, as it is a mammalian hormone.

The examiner rejected the claims based on the fact that antibodies to CP33 inhibited Chlamydia and therefore, this antibody binds to mannose-6-phosphate receptor as known in the art (see Kuo et al 1996). Therefore, in the absence of evidence to the contrary, it is inherent that this antibody that binds to mannose-6-phosphate receptor possibly binds to IGF-2 too since IGF-2, binds to mannose-6-phosphate receptor.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (703) 308-8886. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Padma Baskar Ph.D.

8/1103


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER

8/14/03